

Notice of Allowability**Application No.**

10/038,509

Applicant(s)

SMITH ET AL.

Examiner

NORA ROONEY

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 03/18/2011.
2. ☒ The allowed claim(s) is/are 1, 3, 6-7, 12-13.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 03/24/2011.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Nora M Rooney/
Primary Examiner, Art Unit 1644

EXAMINER'S AMENDMENT

1. Applicant's response filed on 03/18/2011 has been entered.
2. Claims 1, 3 and 6-7 are pending.
3. The terminal disclaimer filed on 03/18/2011 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,936,426 has been reviewed and is accepted. The terminal disclaimer has been recorded.
4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.
5. Authorization for this amendment was given in a telephone interview with Astrid Spain on March 24, 2011.

In the claims:

6. See the attached "Amendment to the Claims."
7. Claims 1, 3, 6-7 and 12-13 are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 25, 2011

/Nora M Rooney/
Primary Examiner, Art Unit 1644

Amendment to the Claims

1. (previously presented) A method of detecting Graves' disease in a patient comprising
 - (a) obtaining an orbital or skin sample comprising fibroblasts from the patient,
 - (b) contacting said fibroblasts with disease specific IgG from the same patient, and
 - (c) detecting in said orbital or skin sample binding of disease specific IgG to the IGF-1 receptor (IGF-1R) relative to a control wherein said binding of disease specific IgG to the IGF-1 receptor (IGF-1R) activates fibroblasts, wherein an increased presence of IgG-activated fibroblasts compared to the control indicates Graves' disease, and wherein fibroblast activation is determined by measuring the level of IL-16 expressed by said IgG-activated fibroblasts, RANTES expressed by said IgG-activated fibroblasts or by measuring T cell migration towards said fibroblasts in said orbital or skin sample.
2. (cancelled)
3. (currently amended) The method of claim 1, wherein an elevated level of ~~the marker~~ said IL-16 compared to the control indicates presence of said IgG-activated fibroblasts.
- 4.-5. (cancelled)
6. (currently amended) The method of claim 1, wherein the detecting is accomplished by exposing T-cells to said orbital or skin sample comprising said fibroblasts and measuring T-cell migration toward said fibroblasts, wherein an increase in the migration of said fibroblasts relative to the control indicates presence of said IgG-activated fibroblasts.
7. (currently amended) The method of claim 1, wherein the patient is human.
- 8.-11. (cancelled)

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12. (New) The method of claim 1, wherein an elevated level of said RANTES compared to the control indicates presence of said IgG-activated fibroblasts.
13. (New) The method of claim 1, wherein said increased T cell migration compared to the control indicates presence of said IgG-activated fibroblasts.